

Practitioner's Docket No. U 014781-0

*IFW*  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Buchi Reddy REGURI, et al.

Application No.: 10/649,380

Group No.: 1625

Filed: August 27, 2003

Examiner: Reyes, Hector M.

For: A NEW CRYSTALLINE FORM OF N-(TRANS-4-ISOPROPYLCYCLOHEXANE CARBONYL)-D-PHENYLALANINE AND PROCESS FOR PREPARATION THEREOF

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
BEFORE MAILING DATE OF EITHER A FINAL ACTION  
OR NOTICE OF ALLOWANCE (37 C.F.R. 1.97(c))**

**NOTE:** 37 C.F.R. 1.97: "(c) An information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:

- (1) The statement specified in paragraph (e) of this section; or
- (2) The fee set forth in § 1.17(p)."

**NOTE:** "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

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**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***  
(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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**37 C.F.R. 1.8(a)**

**37 C.F.R. 1.10\* (Preferred)**

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**TRANSMISSION**

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Date: July 20, 2004

*[Signature]*

Janet I. Cord

(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

**NOTE:** 37 C.F.R. § 1.704(d): "A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable."

**NOTE:** "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final. Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63). But see § 103(b) and (c), limited suspension of action in a continued prosecution application (CPA) filed under § 1.53(d) and in a request for continued examination (RCE) under § 1.114.

**WARNING:** No extension of time can be had under 37 C.F.R. 1.136(a) or (b) for filing an IDS. 37 C.F.R. 1.97(f).

#### **TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

1. The information disclosure statement transmitted herewith is being filed **after** three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but **before** the mailing date of either:

- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,

whichever occurs first.

#### **STATEMENT OR FEE**

2. Accompanying this transmittal is  
(check either A or B below)

A.  a statement as specified in 37 C.F.R. 1.97(e).

**OR**

B.  the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00).

#### **METHOD OF PAYMENT OF FEE**

3.  Attached is a check in the amount of \$ 180.00.

[ ] Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.  
A duplicate of this request is attached.

If any additional fees are due, please charge Account 12-0425.

*David Corr*  
**SIGNATURE OF PRACTITIONER**

Reg. No. 33,778

Janet I. Cord  
*(type or print name of practitioner)*

Tel. No.: (212)708-1935

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P.O. Address

Customer No.:

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c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Buchi Reddy REGURI, et al.

Serial No.: 10/649,380

Group No. 1625

Filed: August 27, 2003

Examiner: Reyes, Hector M.

For: A NEW CRYSTALLINE FORM OF N-(TRANS-4-ISOPROPYLCYCLOHEXANE CARBONYL)-D-PHENYLALANINE AND PROCESS FOR PREPARATION THEREOF

Attorney Docket No.: U 014781-0

07/27/2004 SMINASSI 00000018 10649380

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Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

We draw the attention of the Examiner to the attached English-language version of an Action or International-type Search Report from a foreign office in respect of counterpart International Application No. PCT/US03/26880 that indicates the degree of relevance found by the foreign office. The Search Report makes consideration of any non-English art required. MPEP 609.

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**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

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**37 C.F.R. 1.8(a)**

**37 C.F.R. 1.10\***

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Signature

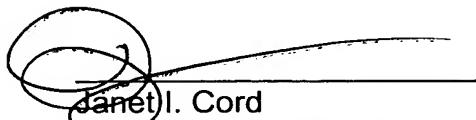
JANET J. CORD

(type or print name of person certifying)

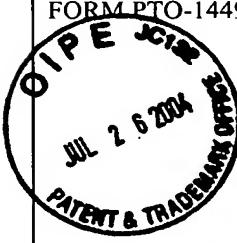
**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).  
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

Form PTO-1449 is also attached with reference copies.

Respectfully submitted,



Janet I. Cord  
c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, NY 10023  
(212) 708-1935

FORM PTO-1449  U. S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)	ATTY. DOCKET NO.	SERIAL NO.
	U014781-0	10/649,380
	APPLICANT	
	Buchi Reddy REGURI, et al.	
	FILING DATE	GROUP
	August 27, 2003	1625
		U.S. PATENT DOCUMENTS

EXAMINER INITIALS	REFERENCE DESIGNATION	DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	5,463,116	10/1995	Michito SUMIKAWA, et al.	
	AB				
	AC				
	AD				
	AE				
	AF				
	AG				
	AH				
	AI				
	AJ				
	AK				

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AL	03/022251	3/2003	WO	X	
	AM	03/087039	10/2003	WO		X
	AN	03/087038	10/2003	WO	X	
	AO	03/093222	11/2003	WO	X	
	AP					

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

	AR	Abstract of Gang Li, Yaowu Fenxi Zazhi (2001), 21 (5), 342-344
	AS	Gang Li, et al., Study on Stability of Nateglinide Polymorphism, Chinese Chemical Letters (2003) Vol. 14, No. 7, pp 730-733
	AT	

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	